

PREVENTIVE CARE
STANDARD PROTOCOL FOR ALL VACCINES
Managing Adverse Reactions

STATEWIDE DRUG THERAPY MANAGEMENT PROTOCOL for the OREGON PHARMACIST

AUTHORITY and PURPOSE: Per ORS 689.645, a pharmacist may provide patient care services pursuant to a statewide drug therapy management protocol.

- Following all elements outlined in OAR 855-115-0330 a pharmacist licensed and located in Oregon may prescribe and administer medications used in the acute management of severe adverse events following immunization in adherence with current CDC ACIP recommendations and Epidemiology, Prevention of Vaccine-Preventable Diseases (Pink Book), and CDC Yellow Book: Health Information for International Travel information.

STANDARDIZED PATIENT ASSESSMENT PROCESS ELEMENTS:

- Utilize the standardized Managing Adverse Events Assessment and Treatment Care Pathway (pg.2)
- Utilize Managing Adverse Events Protocol (pgs. 3-9)
- Utilize Adverse Event Record Tool (Appendix A) & Emergency Kit Medications & Equipment List (Appendix B)
- Refer to Recognizing & Responding to Anaphylaxis (Appendix C)

PHARMACIST TRAINING/EDUCATION:

- The Pharmacist has completed a course of training as outlined in OAR 855-115-0305
- The Pharmacist maintains active CPR certification as outlined in OAR 855-115-0305

RESOURCES

CDC ACIP General Best Practice Guidelines: Preventing and Managing Adverse Reactions-
<https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf>

Epidemiology and Prevention of Vaccine-Preventable Diseases (Pink Book): Vaccine Administration-
<https://www.cdc.gov/vaccines/pubs/pinkbook/vac-admin.html>

Medical Management of Vaccine Reactions in Adults in a Community Setting-
<https://www.immunize.org/catg.d/p3082.pdf>

Medical Management of Vaccine Reactions in Children and Teens in a Community Setting-
<https://www.immunize.org/catg.d/p3082a.pdf>

State of Oregon Trauma and EMS Systems. Treatment of severe allergic reaction; A Protocol for Training (2018).
<https://www.oregon.gov/oha/PH/PROVIDERPARTNERRESOURCES/EMSTRAUMASYSTEMS/Documents/Training%20Material/Epinephrine-Training-Protocol.pdf>

Vaccine Adverse Event Reporting System (VAERS) - <https://vaers.hhs.gov/index>

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Assessment and Treatment Care Pathway

STEP 1: COLLECT

- Observe patient's signs and symptoms
- Obtain prepared Emergency Kit (E-Kit)

STEP 2: ASSESS

- Assess patient's blood pressure and vital signs
- Anaphylaxis should be considered when signs or symptoms are generalized (i.e., if there are generalized hives or more than one body system is involved) or are serious or life-threatening in nature, even if they involve a single body system (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips)
- Activate emergency response (Call 911) if signs and symptoms indicate progression towards anaphylaxis

STEP 3: PLAN

- Prepare treatment medications if indicated
- Prepare for CPR

STEP 4: IMPLEMENT

- Apply treatment plan and/or administer treatment medications per protocol
- If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately and apply AED if available

STEP 5: FOLLOW-UP

- Continue assessing vitals and monitor per protocol until Emergency Medical Services arrive
- Document actions using Adverse Event Record Tool
- Report anaphylaxis and vasovagal syncope to the Vaccine Adverse Events Reporting System (VAERS) online at <https://vaers.hhs.gov/reportevent.html>.
- VAERS Reporting Table: <https://vaers.hhs.gov/resources/infoproviders.html>.

Event and Interval From Vaccination
A. Anaphylaxis or anaphylactic shock (7 days)
B. Vasovagal syncope (7 days)
C. Shoulder Injury Related to Vaccine Administration (7 days)
D. Any acute complication or sequelae (including death) of above events (interval – not applicable)
E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval – see package insert)

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1. What's New

A. N/A

2. Anaphylaxis Protocol (Generalized Symptoms)

- A. If symptoms are generalized, call 9-1-1 immediately. This should be done by a second person if available, while the primary healthcare professional assesses the airway, breathing, circulation, and level of consciousness of the patient. Do not delay transport; DO NOT WAIT FOR MILD SYMPTOMS TO SUBSIDE.
- B. Keep patient in recumbent position (flat on back) unless patient is having breathing difficulty. If breathing is difficult, patient's head may be elevated, provided blood pressure is adequate to prevent loss of consciousness. If blood pressure is low, elevate legs.
- C. Take and record the patients' blood pressure and vital signs (pulse, respirations) at the initial assessment, and at minimum – every 5 minutes, and following the administration of any medication.
- D. The first-line and most important therapy in anaphylaxis is epinephrine. There are NO absolute contraindications to epinephrine in the setting of anaphylaxis.
- E. Administer 1mg/mL epinephrine intramuscularly (IM) into the anterolateral thigh (all ages), through clothing if necessary, with the correct needle length for the patient's age and size according to the dosage chart in Table 1.
- F. If no improvement in condition, repeat epinephrine dose every 5–15 minutes for up to 3 doses, depending on patient's response.
- G. Complete the Adverse Event Record Tool.
- H. If at any time the patient suffers Respiratory or Cardiac Arrest, start CPR immediately. Apply AED if available.
- I. Monitor until Emergency Medical Services arrive.
- J. Any patient who develops signs and symptoms of anaphylaxis MUST be transported via a fully equipped emergency vehicle to an emergency department. Any refusal of transport must be handled by EMS personnel.
- K. Give report and list of medications given to emergency medical personnel upon arrival.
- L. Medication Schedule: *See Table 1 on next page*

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Table 1: Anaphylaxis

<p>Inject EPINEPHRINE (1mg/mL): 0.01 mg/kg of body weight up to 0.5mg maximum dose. <u>May be repeated every 5–15 minutes for a total of 3 doses.</u> Give intramuscularly (IM) in the vastus lateralis muscle of the thigh, <u>regardless of age</u>, either by auto injector or by syringe and needle, <u>through the clothing if necessary.</u>¹</p>				
Suggested dosing of Epinephrine for children ² and adults: consider needle length				
Age Group	Weight in lb [#]	Weight in kg [#]	Epinephrine injectable (1:1000 dilution); IM =(1mg/mL) [Minimum dose: 0.05mL]	Epinephrine auto-injector 0.1mg (7.5-14.5 kg), 0.15mg (15-29.5 kg) or 0.3 mg (≥30 kg)
6 months (use only for dosing by weight)	9-16 lb	4-7 kg	0.05 mL (or mg)	Off-Label
	16.5-19 lb	7.5-8.5 kg		0.1mg/dose*
7-36 months (use only for dosing by weight)	20-32 lb	9-14.5 kg	0.1 mL (or mg)	0.1mg/dose*
37-59 months	33-39 lb	15-17.5 kg	0.15 mL (or mg)	0.15mg/dose
5-7 years	40–56 lb	18–25.5 kg	0.25 mL (or mg)	0.15mg/dose
8–10 years	57–76 lb	26–34.5 kg	0.3 mL [†] (or mg)	0.15 mg/dose or 0.3mg/dose
11–12 years	77–99 lb	35–45.5 kg	0.4 mL (or mg)	0.3mg/dose
≥13 years	100+ lb	46+ kg	0.5 mL [‡] (or mg)	0.3mg/dose

[#]Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months. Round kg to nearest 0.5 kg.

* The 0.15mg epinephrine autoinjector can also be used for children 7.5 kg (16.5 lb) to 14.5 kg (32 lb) when other alternatives are not available.

[†]Maximum dose for children (prepubertal)¹

[‡]Maximum dose for adolescents and adults¹

3. Urticaria Protocol (Localized Symptoms)

- A. If itching and swelling are confined to the injection site where the vaccination was given, observe patient closely for the development of generalized symptoms.
- B. Apply ice to the site where the vaccine was administered. If more than one site is involved, apply ice to the sites that appear to be red, warm, or swelling.
- C. Administer diphenhydramine intramuscularly (IM) with the correct needle length for the patient’s age and size according to the dosage chart in Table 2.
- D. Administer hydroxyzine hydrochloride orally if diphenhydramine unavailable according to patient’s age and size in the dosage chart in Table 3.
- E. Complete the Adverse Event Record Tool.
- F. Take and record the patient’s blood pressure and vital signs at the initial assessment, and at minimum - every 10 minutes, and following the administration of any additional medication.

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- G. Continue to monitor for and treat signs and symptoms progressing towards anaphylaxis when indicated. If signs and symptoms present, immediately initiate anaphylaxis protocol.
- H. Medication Schedule:

Table 2: Urticaria

First-Line Treatment for Urticaria: Give Diphenhydramine IM as follows:			
Suggested dosing of Diphenhydramine for children² and adults			
Age Group Dose	Weight in lbs[#]	Weight in kg[#]	Injectable: 50mg/mL IM[†]
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	5-10 mg (0.1 - 0.2 mL)
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	10-15 mg (0.2 - 0.3 mL)
37-59 months	33-39 lbs	15-17.5 kg	15-20 mg (0.3 - 0.4 mL)
5-7 years	40-56 lbs	18-25.5 kg	20-25 mg (0.4 - 0.5 mL)
8-12 years	57-99 lbs	26-45.5 kg	25-50 mg (0.5 - 1.0 mL)
≥13 years[‡]	100+ lbs	46+ kg	50-100 mg (1 - 2 mL) [*]

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 1-2mg/kg

[‡] Maximum single dose is 100mg for persons ≥13 years²⁻³

^{*} No more than 1 mL per injection site

Table 3: Optional Treatment: Hydroxyzine Hydrochloride

Hydroxyzine Hydrochloride for urticaria when Diphenhydramine is unavailable: Give PO as follows:			
Suggested dosing of Hydroxyzine Hydrochloride for children² and adults			
Age Group Dose	Weight in lbs[#]	Weight in Kg[#]	Liquid: 10mg/5mL or 25mg/5mL[†]
6 months (use only for dosing by weight)	9-19 lb	4-8.5 kg	2.5-5 mg/dose
7-36 months (use only for dosing by weight)	20-32 lbs	9-14.5 kg	5-7.5 mg/dose
37-59 months	33-39 lbs	15-17.5 kg	7.5-10 mg/dose
5-7 years	40-56 lbs	18-25.5 kg	10-12.5 mg/dose
8-10 years	57-76 lbs	26-34.5 kg	12.5-15 mg/dose
11-12 years	77-99 lbs	35-45.5 kg	15-25 mg/dose
≥13 years	≥100 lbs	≥46 kg	25 mg/dose

[#] Dose by weight is preferred. If weight is not known, dosing by age is appropriate for ages >36 months.

[†] Pediatric dose is 0.5-1 mg/kg

^{*} Maximum single dose is 25mg for persons ≥13 years²⁻³

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4. Loss of Consciousness/Syncope Protocol

- A. If the individual “feels faint”, ammonia ampules should be used if available. Crush and wave near patient’s nose.
- B. Have patient lie flat with feet elevated or sit with their head down for several minutes.
- C. If the patient loses consciousness, place flat on back, with feet elevated.
- D. Unconsciousness from fainting should only last seconds. In a vasovagal response, the pulse should be slow. A weak, thready or rapid pulse may indicate anaphylaxis. Continue to monitor for signs and symptoms progressing towards anaphylaxis. If signs and symptoms present, immediately initiate anaphylaxis protocol.
- E. Have patient rest in a quiet area for 10 minutes after regaining consciousness. Slowly have patient move to a sitting position and then standing, checking to make sure no symptoms recur.
- F. Complete the Adverse Event Record Tool.

5. Contraindications

- A. There are **no** contraindications for the use of epinephrine to treat anaphylaxis
- B. Previous hypersensitivity is a contraindication for diphenhydramine and hydroxyzine.
- C. Do not administer epinephrine auto-injector to children weighing less than 16.5 lbs.

6. Other Considerations

- A. Required Documentation:
 - Current Healthcare Provider CPR Card as required by OAR 855-104-0055
 - Completed Adverse Event Record Tool for each event (Appendix A).
- B. Required Medications & Equipment: See Emergency Kit Medications & Equipment List (Appendix B)

7. Storage and Handling

- A. Store medications according to OAR 855-041-1036.

8. Adverse Events Reporting

- A. Anaphylaxis and vasovagal syncope must be reported to the Vaccine Adverse Events Reporting System (VAERS) online at: <https://vaers.hhs.gov/reportevent.html>.
- B. VAERS Table of Reportable Events Following Vaccination:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

9. References

1. CDC. Management of Anaphylaxis at a COVID-19 Vaccination Location. Last updated 11 February 2022. Available at: <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/managing-anaphylaxis.html> Accessed 23 August 2022.
2. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Children and Teens in a Community Setting. July 2019. Available at: <https://www.immunize.org/catg.d/p3082a.pdf>. Accessed 23 August 2022.
3. Immunization Action Coalition Website: Medical Management of Vaccine Reactions in Adults in a Community Setting. July 2019. Available at: <https://www.immunize.org/catg.d/p3082.pdf>. Accessed 23 August 2022.

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10. Appendix

- A. Adverse Event Record Tool
- B. Emergency Kit Medications & Equipment
- C. Recognizing & Responding to Anaphylaxis Reference

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APPENDIX A: Adverse Event Record Tool

Patient Name: _____ Allergies: _____
 Date of Birth: _____ Vaccine(s) Given: _____
 Date: _____ Site(s): _____
 Pharmacist: _____ Route(s): _____

Patient is displaying signs of: Anaphylaxis – Urticaria – Syncope (Circle One)

VITALS							
Time	Pulse	Respirations	Blood Pressure	Medication	Dose	Site–Route	Initials

Notes:

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APPENDIX B: Emergency Kit Medications & Equipment List

Required Medications & Equipment	Quantity/Type	Expiration Date	Optional Medications & Equipment	Quantity/Type	Expiration Date
Epinephrine solutions	1 multi-dose vial (MDV) of 1mg/mL Epinephrine OR Epinephrine auto-injectors; 3 doses each of adult and pediatric size units		Hydroxyzine Hydrochloride for use when Diphenhydramine is unavailable	Liquid: 10 mg/5 mL or 25 mg/5 mL Tablets: 10 mg or 25 mg Capsules: 25 mg	
Diphenhydramine 50 mg/mL injectable	1 multi-dose vial (MDV) OR 2 single-dose vials (SDV) vials		Bottle of water for swallowing oral antihistamines		
Blood Pressure Monitor (with pediatric cuff if applicable)	Automated devices must show current calibration and replace batteries as needed		Sphygmomanometer and Stethoscope (with pediatric cuff if applicable)		
Syringes/Needles	For Epinephrine injection only: 1-cc syringes with 22-25g, 1-1½" needles For Diphenhydramine injection only: 1-3-cc syringes with 22-25g, 1-1½" needles		Ammonia Ampules	1 Box	
Standard injection supplies	N/A				

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APPENDIX C:

Recognizing and Responding to Anaphylaxis

How to recognize anaphylaxis

Healthcare personnel should consider anaphylaxis when patients present with generalized signs or symptoms such as **hives, serious or life-threatening symptoms** (e.g., hypotension, respiratory distress, or significant swelling of the tongue or lips), or **symptoms that involve more than one body system**.



Respiratory:

- sensation of throat closing
- stridor (high-pitched sound while breathing)
- shortness of breath
- wheeze, cough



Gastrointestinal:

- nausea
- vomiting
- diarrhea
- abdominal pain



Cardiovascular:

- dizziness
- fainting
- tachycardia (abnormally fast heart rate)
- hypotension (abnormally low blood pressure)



Skin/mucosal:

- generalized hives
- itching
- swelling of lips, face, or throat



Neurological:

- agitation
- convulsions
- acute change in mental status
- sense of impending doom (a feeling that something bad is about to happen)

What to do if you suspect anaphylaxis



Assess airway, breathing, and circulation



Administer epinephrine



Call Emergency Medical Services (EMS)



Place in supine position

Detailed information can be found in the Interim Considerations:
[Preparing for the Potential Management of Anaphylaxis After COVID-19 Vaccination](#)



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www.cdc.gov/COVID19